

**UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION**

**RELATOR'S RESPONSE IN OPPOSITION TO DEFENDANTS'
MOTION TO DISMISS THE THIRD AMENDED COMPLAINT**

INTRODUCTION

Relator alleges that Defendants submitted thousands of false claims to Medicare in violation of the physician certification requirements found in 42 C.F.R. § 424.22, pursuant to which physician certifications must be made at the time the patient's plan of care is established, or as soon thereafter as possible. *See* 42 C.F.R. § 424.22(a)(2). Ruling that Relator's allegations in this case adequately plead legal falsity, the Sixth Circuit explained that "completing the physician certifications months after the fact cannot be said to have been 'as soon as possible' after the plan for a patient's care was established." *U.S. ex rel. Prather v. Brookdale Senior Living Cmtys.*, 838 F.3d 750, 755 (6th Cir. 2016). "Prather has alleged a violation of this regulation ... by asserting that the certifications were obtained months late due only to the fact

that Brookdale had accumulated a large backlog of Medicare claims, which itself arose solely because of Brookdale’s ‘aggressive solicitation’ of its residents for Medicare-billable treatments that were not always medically necessary or did not need to be performed by nurses who billed to Medicare.” *Prather*, 838 F.3d at 765.

Significantly, the Sixth Circuit also acknowledged the importance of the timing requirement, recognizing that the deadline “makes it more difficult to defraud Medicare.” *Id.* at 764. In view of this fundamental goal, Medicare regulations mandate compliance with this requirement as a condition of payment. *Prather*, 838 F.3d at 766, *citing* 42 C.F.R. § 424.22 and 42 C.F.R. § 409.41.

Based on the Supreme Court decision in *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016), Defendants now ask this Court to declare that the timing requirement is not material to Medicare payment of home health claims, and that Relator has not sufficiently plead scienter in accordance with the False Claims Act. In order to achieve this result, Defendants (1) disregard the plain meaning of the regulations identifying the timing requirement as a condition of payment; (2) diminish the significance of the timing requirement as articulated by the Sixth Circuit; and (3) violate the applicable standard of review by ignoring Relator’s specific allegations demonstrating that Defendants knowingly submitted the false claims.

APPLICABLE LAW

A. Standard of Review

“In the qui tam context, ‘the Court must construe the complaint in the light most favorable to the plaintiff, accept all factual allegations as true, and determine whether the

complaint contains enough facts to state a claim to relief that is plausible on its face.”” *Prather*, 838 F.3d at 761, *citing U.S. ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 502 (6th Cir. 2008). *See also U.S. ex rel. D’Alessio v. Vanderbilt Univ.*, 2014 U.S. Dist. LEXIS 36028, *3 (M.D. Tenn. Mar 19, 2014) (Campbell, J.) (citation omitted). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.*

Although Federal Rule of Civil Procedure 9(b) applies to False Claims Act lawsuits, it “does not require a relator to plead evidence; the Fed.R.Civ.P. 8 requirement that the complaint contain a ‘short and plain statement of the claim’ still applies.” *U.S. ex rel. Cieszyski v. Lifewatch Services, Inc.*, 2015 U.S. Dist. LEXIS 141721, *4 (N.D. Ill. October 19, 2015). “Rule 9(b) exists to prevent spurious charges and provide notice to defendants of their alleged misconduct, not to require plaintiffs to meet a summary judgment standard before proceeding to discovery.” *U.S. ex rel. Bingham v. Baycare Health System*, 2015 U.S. Dist. LEXIS 107220, *11-12 (M.D. Fla. August 14, 2015). *See also U.S. ex rel. Tillson v. Lockheed Martin Energy Systems, Inc.*, 2004 U.S. Dist. LEXIS 22246, *85 (W.D. Ky. September 29, 2004)(Rule 9(b) “was never intended to require a plaintiff to set forth every factual detail supporting its claim.”).

Further, “malice, intent, knowledge and other conditions of a person’s mind may be alleged generally.” Fed. R. Civ. Pro. 9(b). *See also D’Alessio*, 2014 U.S. Dist. LEXIS 36028, *4; and *United States v. Bollinger Shipyards, Inc.*, 775 F.3d 255, 260 (5th Cir. 2014) (“Knowledge need not be pled with particularity under Rule 9(b); it need only be pled plausibly pursuant to Rule 8.”).

“Factual questions …cannot be resolved at the motion to dismiss stage.” *U.S. ex rel. Shemesh v. CA, Inc.*, 89 F. Supp. 3d 36, 48 (D.D.C. 2015). “Rule 9(b) is analyzed case by case.” *Id.* at 52.

B. Medicare Regulations

As recognized by the Sixth Circuit, Medicare “pays for home health services only if a physician certifies and recertifies’ the patient’s eligibility for and entitlement to those services.” *Prather*, 838 F.3d at 755, quoting 42 C.F.R. § 424.22. Pursuant to 42 C.F.R. § 424.22, physicians must certify that (a) “a plan for furnishing the services has been established and is periodically reviewed by a physician;” (b) “the services were furnished while the individual was under the care of a physician;” and (c) the required face-to-face encounter has taken place. *See* 42 C.F.R. § 424.22(a).

“These certifications provide ‘a forward-looking projection of medical need at the time the beneficiary’s plan of care is established,’ ensuring that a patient receives Medicare services only to the extent she needs them.” *Prather*, 838 F.3d at 756, citing United States’ Statement of Interest Regarding Defendants’ Motion to Dismiss, Dkt. 66, Page ID# 860.

As noted above, this Medicare condition of payment explicitly requires that “**the certification of need for home health services must be obtained at the time the plan of care is established or as soon thereafter as possible and must be signed and dated by the physician who establishes the plan.**” 42 C.F.R. § 424.22(a)(2) (emphasis added).

The Sixth Circuit’s opinion in this case recognizes that these certifications are also required for Medicare payment pursuant to 42 C.F.R. § 409.41, noting that “[i]n order for home health services to qualify for payment under the Medicare program the following requirements

must be met: . . . (b) [t]he physician certification and recertification requirements for home health services described in § 424.22.” *Prather*, 838 F.3d at 766, citing 42 C.F.R. § 409.41. In so ruling, the Sixth Circuit emphasized that “**the same certification requirement—and the same timing requirement for that certification—is applied by the regulatory subpart on which Brookdale relies.**” *Id.* (emphasis added).

SUMMARY OF RELEVANT FACTS

The following relevant facts are taken from the Third Amended Complaint (“Complaint”), Dkt. 98.

A. Background

Brookdale Senior Living owns retirement communities and assisted living facilities throughout the United States where it offers skilled nursing services to Medicare patients. Brookdale Senior Living is a principal of ISC Home Health and ARC/ISC. All defendants share the same corporate office. According to documents provided to Brookdale employees, “Innovative Senior Care is Brookdale’s ancillary rehabilitation and wellness organization.” ISC Home Health provides home health care services to Medicare beneficiaries. ISC Home Health and/or ARC/ISC staff solicit referrals from the retirement community staff members on a daily basis. (Complaint ¶¶ 66-69).

To generate additional home health care and therapy revenue, Brookdale Senior Living implemented aggressive marketing practices that were designed to fulfill its reigning philosophy: “most every resident will need therapy or nursing intervention at some point.” (Complaint ¶¶ 70-73). Ultimately, Defendants’ aggressive marketing and solicitation policies generated a backlog of thousands of claims for home health care services that did not comply with Medicare

regulations. To facilitate billing Medicare for these claims, Defendants implemented the Held Claims Project. (Complaint ¶ 74).

B. The Held Claims Project

In September of 2011, there was a large backlog of about 7,000 unbilled Medicare claims worth approximately \$35 million. These claims were referred to as “held claims.” The claims were backlogged because they were not in compliance with Medicare rules, primarily because they related to care that was provided without physician certifications of need for home health services; without properly established plans of care; and/or without required face to face encounter documentation. (Complaint ¶ 77).

Until September of 2011, each office location of ISC Home Health and ARC/ISC submitted its own claims directly to Medicare. At that time, Brookdale Senior Living made the decision to centralize the billing of most of the office locations (“agencies”) into its Brentwood, Tennessee corporate headquarters. (Complaint ¶ 76). Following the transition, copies of patient charts concerning the held claims were forwarded to the Brentwood office to be audited and billed to Medicare. This project was referred to as the “Held Claims Project.” (Complaint ¶ 78).

Relator was employed by Brookdale Senior Living as a utilization review nurse (“UR nurse”) from September of 2011 through November 23, 2012. Relator was hired to work on the “Held Claims Project” and she was terminated when it ended. (Complaint ¶ 75).

Relator was directly involved in the Held Claims Project. Relator’s primary responsibilities included without limitation (1) pre-billing chart reviews in order to ensure compliance with the requirements and established policies of Defendants, as well as state, federal and insurance guidelines; (2) working directly with the Regional Directors, Directors of

Professional Services, and clinical associates to resolve documentation, coverage, and compliance issues; (3) acting as resource person to the agencies for coverage and compliance issues; (4) reviewing visits utilization for appropriateness pursuant to care guidelines and patient condition; and (5) keeping Directors of Professional Services apprised of problem areas requiring intervention. All of these responsibilities directly related to Defendants' efforts to bill the held claims to Medicare. (Complaint ¶ 80).

For each held claim, Defendants used a "billing release checklist" to identify items that needed to be completed before the claim could be released for final billing to Medicare. Once the checklist was finished, it would be attached to the AR Transaction Report, which listed the nursing and therapy visits and the charges to be billed to Medicare. The combined document would then be taken to the employees in the billing office. As soon as the Medicare billing employees received this documentation, they immediately submitted the final bill to Medicare. Miaona Osborne was the Medicare supervisor of the employees in the billing office. (Complaint ¶ 82).

Throughout the duration of the Held Claims Project, senior executives urged Relator and others to expedite the process of releasing the claims for billing to Medicare, and told them to ignore compliance problems that slowed down the process. (Complaint ¶¶ 86-96). One of these executives, Shad Morgheim, sent an email on April 25, 2012, addressed to Relator and others working on the Held Claims Project, in which he announced the decision to move the audit process back to the agencies for all claims older than 120 days. In this email, Mr. Morgheim acknowledged that "[m]ost held claims that are older than 120 days, typically are held up for FTF, orders, or certifications," and complained that "we need to get these released in a quicker

fashion.” Mr. Morgheim emphasized that “[t]here is a high sense of urgency to get these released ASAP.” (Complaint ¶¶ 88-89).

On May 17, 2012, Mr. Morgheim sent an email to Relator and others working on the Held Claims Project, acknowledging that Defendants faced a “looming financial crisis related to the held claims issue.” In order to expedite the process of releasing the oldest held claims, he announced a new “strategy to help compensate physicians for the time they will spend with us to release these claims.” (Complaint ¶ 97).

On May 23, 2012, Mr. Morgheim followed up with another email to Relator and others working on the Held Claims Project, outlining the policy in which Defendants paid physicians to review outstanding held claims and sign orders for previously provided care. This email included several attachments, including a document containing guidance for employees who encountered physicians who did “not want to sign a document,” acknowledging that “if the physician is not comfortable with signing a document then we can not force this process.” Clearly, Defendants anticipated that some doctors would not be “comfortable” with Defendants’ policy of paying doctors to certify stale claims for home health care services. (Complaint ¶ 98).

As the Medicare supervisor of the employees in the billing office, Miaona Osborne was directly involved in billing RAPs, including re-billing them when they were canceled because the final bill was not submitted timely pursuant to 42 CFR 409.43(c)(2), which states that RAPs “will be canceled and recovered unless the claim is submitted within the greater of 60 days from the end of the episode or 60 days from the issuance of the request for anticipated payment.” Pursuant to this process, Defendants billed RAPs without having physician certifications, and then re-billed them immediately after the RAPs were canceled in order to keep the funds

received through the RAPs, while still lacking the required physician certifications. This was done repeatedly on a widespread basis for the subject held claims. (Complaint ¶ 99).

Miaona Osborne's participation in RAP billing and re-billing is reflected in her email dated June 8, 2012, in which she states: “[j]ust wanted everyone to know that there is a ongoing issue at IMP/RCH. It seems as though there is a trend of no orders for nursing in the recert episode and there are a lot of 1st billable charges in the recert episode that we have had to delete. When we are doing this we are having to cancel the Rap with Medicare, wait until the cancellation is complete, then bill the correct rap and then either re-bill the final or correct the final that was rejected. **I just wanted everyone aware that this may trigger a probe or review by Medicare.**” (emphasis added) (Complaint ¶ 100).

In an email dated June 21, 2012, Sonja Nolan informed others working on the Held Claims Project that she had just “sent over 100 pages of Physicians orders to be signed. We have a follow up plan in place to get these expedited. We are working the oldest claims and while waiting on signed documents plan to grab the low hanging fruit, this way we will stop the newer claims from aging.” (Complaint ¶ 102).

In the rush to get held claims paid by Medicare, Defendants implemented incentive programs for COAs and the management of home care agencies for completion of home care plans. For example, a COA received one hundred dollars (\$100) a week if ten (10) claims were submitted to the utilization review department for billing and twenty-five (\$25) for every claim over and above the first ten (10). Angela Spalding, a COA, told Relator that during the week of July 9 through 13, 2012, she completed more than fifty (50) releases to UR nurses resulting in a bonus to her of \$1,200 that she shared among her office peers. (Complaint ¶ 103).

In an email dated July 11, 2012, Sonja Nolan updated her co-workers regarding “**the plot to visit Physicians for orders.**” (Emphasis added). This email reflects that 21 physician certification orders were obtained that day, including one for an episode of care dated May 25, 2011, through July 23, 2011, and another for an episode dated June 29, 2011, through August 27, 2011. Out of the 21 patients identified in this email, 14 involved episodes of care that ended in 2011. (Complaint ¶ 104).

Relator repeatedly told Blackwood and others that she had discovered problems that needed to be addressed, and that Relator was not comfortable knowing the work was not right but still forwarding the claims for billing to Medicare. On more than one occasion during these discussions, Brandi Tayloe, Regional Vice President East-Central Division for ISC Home Health, responded to Relator’s concerns with the statement that “**We can just argue in our favor if we get audited.**” (Complaint ¶ 114).

ARGUMENT

I. Relator’s Third Amended Complaint Pleads Materiality Under the False Claims Act.

A. *Escobar*

In *Escobar*, the Supreme Court reaffirmed that “[t]he term ‘material’ means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” *Escobar*, 136 S. Ct. at 2002 (quoting 31 U.S.C. § 3729(b)(4)). The Court observed that this definition borrows from other federal statutes and descends from the common law, as recognized in earlier Court decisions. *Id.* Courts may analyze materiality from either the

perspective of a “reasonable” person or the particular defendant. *Id.* at 2002-03 (“[A] ‘matter is material’ . . . (1) ‘[if] a reasonable [person] would attach importance to [it] in determining his choice of action in the transaction’; or (2) if the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter ‘in determining his choice of action,’ even though a reasonable person would not.”) (quoting Restatement (Second) of Torts § 538, at 80 (1977)) (second and fourth alterations in original).

The Supreme Court also identified several factors bearing on the materiality inquiry, including whether the requirement is labeled a condition of payment, 136 S. Ct. at 2003, whether the violation goes to the ““essence of the bargain,”” *id.* at 2003 n.5 (quoting *Junius Constr. Co. v. Cohen*, 257 N.Y. 393, 400 (1931)), whether the violation is significant or “minor or insubstantial,” *id.* at 2003, and whether the government took action in this or other cases when it had knowledge of similar violations, *id.* at 2003-04. On remand, the First Circuit observed that “[t]he language that the Supreme Court used in [Escobar] makes clear that courts are to conduct a holistic approach to determining materiality in connection with a payment decision, with no one factor being necessarily dispositive.” *U.S. ex rel. Escobar v. Universal Health Servs. Inc.*, 842 F.3d 103, 109 (1st Cir. 2016).

B. The Physician Certification Requirements Described in 42 C.F.R. § 424.22 are Medicare Conditions of Payment.

Defendants state in their Memorandum in Support of Motion to Dismiss (“Def.Mem.”) that “when Congress or CMS wants to make timing a condition of payment, it knows how to do so.” Def.Mem. at 13. Relator agrees, and submits as an example the unmistakable language employed by CMS in 42 C.F.R. § 409.41 (labeled “Requirement for Payment”): “[i]n order for

home health services to qualify for payment under the Medicare program the following requirements must be met: . . . (b) [t]he physician certification and recertification requirements for home health services described in § 424.22.”¹

Although Defendants elsewhere acknowledge that 42 C.F.R. § 409.41 sets forth conditions of payment,² for purposes of this argument Defendants contend that “§ 409.41 does not create new conditions of payment, but merely references the conditions of payment ‘described in § 424.22.’” Def.Mem. at 13. While Relator agrees that the requirements of § 424.22 are conditions of payment pursuant to the language of § 424.22, § 409.41 does not exclude from its application any aspect of § 424.22 (particularly the timing requirement), as it unequivocally mandates that the physician certification requirements described in § 424.22 must be met in order for home health services to be paid by Medicare. Crucially, as noted above, the Sixth Circuit held in this case that “**the same certification requirement—and the same timing requirement for that certification—is applied by**” 42 C.F.R. § 409.41. *Prather*, 838 F.3d at 766, *citing* 42 C.F.R. § 409.41. (emphasis added).

Defendants unfounded limitation of § 409.41 works in tandem with their distortion of § 424.22, to effectively dilute the physician certification requirement in a manner that CMS clearly did not intend. Defendants ask this Court to rule that while the content of the certification is important for payment, the manner in which the certification is effectuated is not. Such a

¹ Defendants also refer to § 424.22(c), but that provision does not affect the resolution of their motion to dismiss. Def.Mem. at 4. This amendment to the regulation became effective on January 1, 2015, after the relevant claims had already been submitted to Medicare, in conjunction with a modification to the face-to-face requirement. *See* 79 Fed.Reg. No. 66032, 66050, 66117 (Nov. 6, 2014).

² *See* Def.Mem. at 4 n.1 (“Medicare also conditions payment on the beneficiary’s actually being homebound and actually needing skilled services. *See* 42 C.F.R. § 409.41(c) (conditioning payment on all requirements contained in §§ 409.42-409.47 being met.”) and Dkt. 79, Page ID# 1038 (“Medicare conditions payment on the physician’s certification that the beneficiary is homebound and in need of skilled services. 42 C.F.R. § 409.41(b).”).

construction would open the door to the types of fraud that the Sixth Circuit recognized the timing requirement was designed to prevent. *Prather*, 838 F.3d at 764. Moreover, Defendants' strained interpretation also weakens § 424.22(d), which mandates that the "need for home health services to be provided by [a home health agency] may not be certified or recertified, and a plan of care may not be established and reviewed, by any physician who has a financial relationship as defined in § 411.354 of this chapter, with that [home health agency]." See § 424.22(d). Defendants' view of § 424.22 is not justified by the language or the purpose of the rule, is not consistent with the Sixth Circuit's opinion in this matter, and does not provide a basis to dismiss this case.³

C. ***Escobar* Does Not Mandate Allegations Regarding Prior Payment Decisions.**

Defendants characterize *Escobar* as offering the guidepost that "'proof of materiality' includes 'evidence that the defendant knows the Government consistently refuses to pay claims in the mine run of cases based on' the violation alleged." Def.Mem. at 11, *citing Escobar*, 136 S. Ct. 2003. To clarify, the language used by the Supreme Court reads as follows: "'proof of materiality **can** include, **but is not necessarily limited to**, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on" the violation alleged. *Escobar*, 136 S. Ct. 2003 (emphasis added). Thus, this type of allegation is simply one factor that is relevant to the materiality analysis.

Defendants assert that allegations about "prior payment decisions are vital because they relieve the court from having to 'opine in the abstract' about materiality." Def.Mem. at 14, *citing*

³ Defendants' argument that "the specific governs the general," Def.Mem. at 13, fails because § 409.41 is not "general," as it explicitly states that the physician certification requirements of § 424.22 must be met for purposes of Medicare payment. In any event, the Sixth Circuit has already recognized that § 409.41 applies to the timing requirement. *Prather*, 838 F.3d at 766, *citing* 42 C.F.R. § 409.41.

U.S. ex rel. McBride v. Halliburton Co., 848 F.3d 1027, 1032 (D.C. Cir. 2017). Notably, *McBride* was decided with a factual record on summary judgment and did not involve a condition of payment. *Id.* at 1033. Moreover, the court characterized the relator’s allegations as appearing to “shift between imprecise theories about unreasonable costs and faulty supporting documentation.” *Id.* at 1032. This case clearly presents a different scenario, as Relator asserts the widespread violation of an express condition of payment, with allegations the Sixth Circuit has already found to be sufficiently precise.

Similarly, *U.S. ex rel. Schimelpfenig v. Dr. Reddy’s Labs. Ltd.*, No. CV 11-4607, 2017 WL 1133956 (E.D. Pa. Mar. 27, 2017), does not support dismissal in this case. In *Schimelpfenig*, the relator did not allege a violation of a condition of payment, *id.* at *7, and the court found that the relator did not allege a valid claim for legal falsity. *Id.* at *6.

Defendants’ reliance on *U.S. ex rel. Scharff v. Camelot Counseling*, No. 13-cv-3791, 2016 WL 5416494 (S.D.N.Y. Sept. 28, 2016) is also misplaced, as that complaint failed to satisfy Rule 9(b), *id.* at *6, did not allege a violation of a condition of payment, *id.* at *8 n.2, and did not explain why the fraudulent conduct was material. *Id.* at *8.

Likewise, *Knudsen v. Sprint Commc’ns. Co.*, No. C13-04476, 2016 WL 4548924 (N.D. Cal. Sept. 1, 2016) does not support dismissal here, as that complaint did not satisfy Rule 9(b), *id.* at *7, and did not allege that the government was unaware of the subject violations. *Id.* at *13.

In this case, Relator alleges that the United States was “unaware of the falsity of the claims that Defendants submitted,” and paid Defendants “for claims that would otherwise not have been allowed.” Complaint, ¶ 125. There is nothing in the record to indicate otherwise.

Moreover, following the filing of this action, the government has given no indication that the timing requirement is not significant, and in fact has explicitly stated otherwise. Complaint, ¶¶ 50-51. Defendants' claim that this guidance has "no relevance here," Def.Mem. at 19,⁴ is inconsistent with their argument that evidence concerning government payment decisions following the investigation of a lawsuit's allegations is "'strong evidence' that the requirements in those regulations are not material." Def.Mem. at 16, *citing Abbott v. BP Expl. & Prod., Inc.*, 2017 WL 992506, at *3 (5th Cir. Mar. 14, 2017).

D. The Physician Certification Deadline is Necessary to Prevent Medicare Fraud.

Interpreting the timing requirement, the Sixth Circuit explained its importance:

By its nature, [as soon thereafter as possible] **suggests urgency**. So too here. Nor is it surprising that such language would be used in this context. Doctors are busy, and they may see a large number of patients in a given year. Although it may be easy for a doctor to remember shortly after an appointment that she met with a particular patient on a particular day, found that the patient needed home-health services, and established a plan for providing those services to the patient, it likely would be much harder to remember this information months later. **The deadline also makes it more difficult to defraud Medicare.** Absent a deadline, a home-health agency might be able to provide unnecessary treatment absent a doctor's supervision and take the time to find doctors who are willing to validate that care retroactively. **A deadline allowing only a short—and justified—delay between the beginning of care and the completion of the physician certification could make such a scheme difficult to pull off.**

Prather, 838 F.3d at 764 (emphasis added). The Sixth Circuit's analysis is consistent with guidance issued by the Office of Inspector General for the Department of Human Resources ("OIG"). Complaint, ¶¶ 47-49. For example, the OIG has identified "untimely and/or forged

⁴ While the Sixth Circuit ruled that this guidance did not set a "hard rule" in light of the regulation's "flexible 'as soon thereafter as possible' language," it did not hold that the guidance is not relevant for any purpose. *Prather*, 838 F.3d at 765 n.6.

physician certifications on plans of care” as a special area of concern, and has described the importance of the “dual role” of physicians by emphasizing that the “physician role has become one of ‘gatekeeper’ at the onset, ensuring that the patient is eligible for Medicare home health services.” Complaint, ¶ 47, 49, *citing The Physician’s Role in Medicare Home Health 2001*” at 4 (<https://oig.hhs.gov/oei/reports/oei-02-00-00620.pdf>).

E. The Authorities Identified in the Complaint Demonstrate Materiality.

While Defendants dismiss the Complaint’s reference to the certifications contained in CMS Form 855A as a “one-off, irrelevant” authority, Def.Mem. at 17, they completely ignore Relator’s allegations identifying Defendants’ misrepresentations regarding physician certifications when they submitted the false claims to Medicare. Complaint, ¶¶ 34-38. In utilizing Form 1450 to bill Medicare, Defendants explicitly certified that “[p]hysician’s certifications and re-certifications, if required by contract or Federal regulations, are on file.” Complaint, ¶ 37. These certifications were false and misleading because the physician certifications in connection with the subject claims did not satisfy the material requirement that they be obtained at the time the plans of care were established or as soon thereafter as possible. Complaint, ¶ 124. Pursuant to *Escobar*, Defendants’ “failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.” *Escobar*, 136 S. Ct. at 2001.

Defendants also assert that the OIG guidance identified in Paragraph 47 of the Complaint “is irrelevant here because it relates only to 42 C.F.R. § 409.43(c)(3).” Def.Mem. at 18. *See* 63 Fed.Reg.No. 42410 (August 7, 1998). To the contrary, the guidance specifically references the requirements of 42 C.F.R. § 424.22. *Id.* at 42414 n.33, 42416 n.55 and 42417 n.58.

Defendants next point to the section relating to the “Claim Development and Submission Process,” Def.Mem. at 18, which provides that “[p]articular attention should be paid to issues associated with medical necessity, homebound status of beneficiary, physician certification of plan of care, and qualifying services to establish coverage eligibility.” 63 Fed.Reg. at 42415. This section warns providers to “take all reasonable steps to ensure that claims for home health services are ordered and authorized by a physician,” *id.* at 42416, pursuant to the requirements of “42 CFR 424.22(a) and (b).” *Id.* at 42416 n.55. While Defendants assert that “the signature-timing requirement in § 424.22(a)(2) is not identified as one of those areas of concern,” Def.Mem. at 18-19 (emphasis in original), they do not explain how the specific reference to 42 C.F.R. § 424.22(a) does not identify 42 C.F.R. § 424.22(a)(2).

Significantly, this guidance also explains that a “home health agency cannot avoid liability for filing improper claims simply because a physician has ordered the services,” noting that “Medicare . . . imposes a duty to investigate the truth, accuracy, and completeness of claims before they are submitted.” 63 Fed.Reg. at 42416-42417 n.55.⁵

Defendants argue that the guidance described in Paragraph 48 of the Complaint “merely recites the language in § 424.22(a)(2) and says nothing about whether the Government would deny claims based on any violation.” Def.Mem. at 19 n.8. In response, Relator respectfully submits that the OIG’s explicit identification of the timing requirement in a “Special Fraud Alert” further demonstrates the materiality of the requirement.

⁵ Relator further notes that this guidance directs home health agencies to “[p]rovide that the compensation for billing department personnel and billing consultants should not offer any financial incentive to submit claims regardless of whether they meet applicable coverage criteria for reimbursement.” 63 Fed.Reg. at 42415. Defendants’ compensation of billing department employees in connection with the Held Claims Project raises issues regarding their compliance with this guidance, and is relevant to this Court’s analysis of the scienter requirement. Complaint, ¶ 103.

II. The Complaint Properly Alleges That Defendants Knowingly Submitted False Claims.

The False Claims Act requires that false claims be submitted “‘knowingly,’ i.e., with actual knowledge of the information, or with deliberate ignorance or reckless disregard for the truth or falsity of the claim.’” *Prather*, 838 F.3d at 761 (citation omitted). Complaint, ¶ 64. In *Escobar*, the Supreme Court recognized that “the Act’s scienter requirement ‘require[s] no proof of specific intent to defraud.’” *Escobar*, 136 S. Ct. at 1999 n.2. Especially in light of the rule that knowledge may be alleged generally, Fed. R. Civ. Pro. 9(b), Relator’s Complaint is more than sufficient to allege scienter.⁶

Initially, Relator notes that Defendants concede that a “defendant can have actual knowledge that a requirement is material if ‘the Government expressly call[s] it a condition of payment.’” Def.Mem. at 23 *citing Escobar*, 136 S. Ct. at 2002. The express language of 42 C.F.R. § 409.41 and 42 C.F.R. § 424.22, as noted above, demonstrates Defendants’ actual knowledge of materiality in this case.

While Defendants proceed to construe every inference of the allegations in the Complaint in their favor (contrary to the standard of review applicable to their motion), the allegations that they do not mention are more than sufficient to establish scienter.

Defendants’ senior executives were specifically aware that held claims did not have proper physician certifications. Complaint, ¶ 89. When Relator and others identified these compliance problems, they were told to ignore them. Complaint, ¶ 91. In fact, Defendants specifically instructed Relator and others not to look for problems related to Medicare billing,

⁶ In its opinion granting Defendants’ Motion to Dismiss Relator’s First Amended Complaint, this Court found that the requirement to plead intent had been met. Dkt. 71 at 33 n.10.

Complaint, ¶ 91, and to ignore any compliance issues regarding information in the records. Complaint, ¶ 87.

Relator's allegations regarding Defendants' payments to doctors to certify stale claims are also relevant to the scienter analysis, especially considering that Defendants acknowledged that some doctors might not be comfortable with signing documents under those circumstances. Complaint, ¶¶ 97-98.

In response to Relator's repeated efforts to alert management that the claims did not comply with Medicare conditions of payment, Defendants bluntly stated that "**[w]e can just argue in our favor if we get audited.**" Complaint, ¶ 114. *Prather*, 838 F.3d at 757-758. In this context, Miaona Osborne's email on June 8, 2012, is particularly illuminating, as she issues the following warning to others regarding their RAP billing and re-billing: **I just wanted everyone aware that this may trigger a probe or review by Medicare.**" (emphasis added) (Complaint ¶ 100).

III. The Complaint Adequately Pleads a Reverse False Claim.

Defendants argument that the Complaint does not adequately state a reverse false claim is based on the same arguments they assert with respect to Relator's other claim. Def.Mem. at 24. For the reasons discussed above, the Complaint's reverse false claim allegations satisfy the requirements of the False Claims Act.

CONCLUSION

Based on the above and on the detailed allegations in the Third Amended Complaint, Relator has satisfied the requirements of Federal Rule 9(b) and Rule 12(b)(6). Accordingly,

Defendants' motion to dismiss should be denied. Alternatively, Relator respectfully requests leave to file an amended complaint to address any concerns the Court may have.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document has been served upon the following counsel via e-mail on this 1st day of May, 2017.

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